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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,378	10/24/2001	Li Li	21402-179 (CURA-479)	8388

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EXAMINER
SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,378	LI ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 29, and 32, drawn to isolated polypeptides, classified in class 530, subclass 350.

II. Claims 5-14, 30, and 33, drawn to isolated nucleic acids, classified in class 536, subclass 23.1.

III. Claims 15-17, 31, and 34, drawn to antibodies, classified in class 530, subclass 387.1.

IV. Claim 18 and 38, drawn to methods for detecting polypeptides which utilize antibodies acids and the detection of a predisposition to disease via polypeptide detection, classified in class 435, subclass 7.1.

V. Claims 19 and 39, drawn to methods for detecting nucleic acids and the detection of a predisposition to disease via nucleic acid detection, classified in class 435, subclass 6.

VI. Claims 20-22, drawn to methods for identifying agents that bind polypeptides and modulate expression, classified in class 436, subclass 501.

VII. Claims 23-24, 35, and 40, drawn to methods for treatment comprising administering polypeptides, classified in class 514, subclass 2.

VIII. Claims 25-26 and 35, drawn to methods for treatment comprising administering nucleic acids, classified in class 514, subclass 44.

IX. Claims 27-28, 35, and 41, drawn to methods for treatment comprising administering antibodies, classified in class 424, subclass 130.1.

X. Claims 36-37, drawn to methods for screening for modulators comprising administering a test compound to a transgenic animal, classified in class 800, subclass 3.

Further Restriction Applicable to All Groups

Each group detailed above reads on 15 patentably distinct groups, wherein each of the distinct characterized by the presence of or the utilization of a particular nucleic acid or polypeptide identified by a specific SEQ ID NO. Applicants must further a single nucleic acid or polypeptide, as appropriate, for examination with whichever claim set is elected. Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims. Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I, II, and III are patentably distinct because they are drawn to different products having different structures and functions. The polypeptide of Group I is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The nucleic acid of Group II is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The antibody of Group III is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific

tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups I, II, and III can be used in materially different processes, for example, the DNA of Group II can be used in hybridization assays, the antibody of Group III can be used in immunoassay, the polypeptide of Group I can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, and III are patentably distinct from each other.

3. Inventions I is related to inventions IV, VI, and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention I can be used in a variety of methods, as exemplified herein, and further in methods for raising antibodies and making fusion proteins.

4. Invention I is unrelated to inventions V, VIII, IX and X. Invention II is unrelated to inventions IV, VI, VII, IX, and X. Invention III is unrelated to inventions V, VI, VII, VIII, and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as being used together as the methods of inventions V, VIII, IX, and X do not require or utilize

the polypeptides of invention I. Likewise, the methods of inventions IV, VI, VII, IX, and X do not require or utilize the polynucleotides of invention II, and the methods of inventions V, VI, VII, VIII, and X do not require or utilize the antibodies of invention III.

5. Inventions II and V and inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention II can be used in a variety of methods as is exemplified by groups V and VIII. In addition the nucleic acids of invention II can be used in nucleic acid purification assays and aptamer assays.

6. Inventions III and IV and inventions III and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of invention III can be used in a variety of methods including, for example, methods of treatment, binding assays, and methods of detection.

7. Inventions IV-X are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods which either have separate goals (effects and functions) for example, detection of nucleic acids or detection of polypeptides or treatment of disease or

screening for compounds, or have different modes of operation, for example, treatment with polypeptide versus nucleic acids versus antibodies. The methods are not disclosed for use together or necessary for the practice of one another. Therefore, they are unrelated.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-X require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper. With regard to the restriction between individual sequences, each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because they do not share a common structure. A reference against one would not anticipate or obviate another, and thus for each particular sequence a separate search of the patent and non-patent literature is required. These separate searches would impose undue burden on the examiner.

9. A telephone call was made to Ivor Elrifi on 4/24/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet Einsmann Switzer whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet Einsmann Switzer
Examiner
Art Unit 1634

May 2, 2003